IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 6 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF RALPH ZIPPER, M.D.

Plaintiffs in the above-captioned cases respectfully submit this Response in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson's Motion to Exclude Certain Opinions of Ralph Zipper, M.D. and Memorandum in support thereof ("Def. Br.").[1]

INTRODUCTION

Plaintiffs have designated Dr. Ralph Zipper as a urogynecology expert who will offer opinion testimony that, among other things: 1) the TVT-SECUR (hereinafter "TVT-S") device was defectively designed; 2) there were safer alternative designs available to Defendants at the time they designed, developed and sold TVT-S; 3) Defendants failed to adequately warn physicians and their patients of the risks that they knew or should have known existed; and 4) Defendants failed to adequately test TVT-S before placing it on the market. In response, the Defendants have moved to exclude the following opinions of Dr. Zipper:

[1] Ethicon adopted its Motion to Exclude Certain Opinions of Dr. Ralph Zipper filed in Wave 1 [Dkt. 2068 and 2072]. Plaintiffs hereby adopt their Wave 1 Response to Defendant Ethicon's Motion to Exclude Certain Opinions of Dr. Ralph Zipper [Dkt. 2190] and serve the within supplemental response.

- Alleged design defect opinions concerning mesh degradation, contraction, and extrusion that require biomaterials expertise;
- Alleged design defect opinions that are not supported by application of a reliable methodology;
- Alleged defective warnings contained in the TVT-S Instructions for Use ("IFU") The *Instructions for Use* (IFU) is inadequate;
- "Safer" alternative products whose comparative safety and efficacy have not been quantified;
- Opinions about Ethicon's alleged knowledge, state of mind and bad acts;
- Opinions that amount to nothing more than historical commentary; and
- Opinions that have not been disclosed in his expert reports.

However, all of these opinions are well within Dr. Zipper's realm of expertise, are reliable and relevant. Notably, on April 21, 2016, Defendants filed a motion challenging Dr. Zipper's general opinions concerning Prolift and Prosima. *See* Exhibit "A". In the present motion (Exhibit "B"), Defendants simply rehash the same stale arguments this Court has already decided and, for the most part, rejected or reserved a ruling until trial *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4944991, at *3 (S.D. W. Va. Sept. 1, 2016) (order denying Ethicon's challenge to Dr. Zipper's qualifications and reliability of his design defect biomaterial opinions, granting its motion concerning certain labeling opinions and reserving ruling on the remaining arguments).

At most, the Court should do what it did in its Wave 1 order concerning Dr. Zipper's expert opinions. However, Dr. Zipper is highly qualified to offer the challenged opinions and based all of his opinions in this case on his extensive review of the medical and scientific

literature, Ethicon's internal documents, his knowledge, training, education, and experience, including his experience consulting for mesh device manufacturers, such as Defendant Ethicon, and his review of relevant deposition transcripts – methods he routinely uses in his clinical practice treating patients and in his role as the CEO of medical device manufacturing companies.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104. *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony). The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). As this Court has previously concluded,

> I "need not determine that the proffered expert testimony is irrefutable or certainly correct" — "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" . . . "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached."

Eghnayem v. Boston Scientific Corp., 57 F. Supp. 3d 658, 669 (S.D.W.Va. 2014).

ARGUMENT

I. Dr. Zipper is qualified to testify on the design of mesh products and the characteristics of polypropylene. His testimony on this subject is reliable and relevant.

As a urogynecologist board-certified in Female Pelvic Medicine and Reconstruction, Dr. Zipper is more than qualified to offer opinions concerning the design of mesh devices, and opine

on the material characteristics of polypropylene. Dr. Zipper has already been deemed qualified to provide nearly identical opinions in a similar case, and is qualified to testify in the instant case.

Indeed, the Defendants made the same stale challenges to Dr. Zipper's qualifications that they rehash in the present matter. In its order denying Ethicon's motion to exclude Dr. Zipper's biomaterials opinions, this court found:

> Ethicon challenges Dr. Zipper's qualification to opine on the biomaterial properties of mesh–which Ethicon describes as opinions on degradation, shrinkage, contraction, and porosity–because he does not have an engineering degree in materials science, nor any background in polymer chemistry or biomechanical engineering. This argument is unavailing. Dr. Zipper is a board-certified pelvic surgeon and urogynecologist who has performed thousands of transvaginal mesh procedures and explanted over 500 mesh devices. Additionally, he has experience developing devices for the treatment of pelvic pain and overactive bladder. This extensive clinical and product development experience, combined with Dr. Zipper's review of the medical literature, qualifies him to opine on the biomaterial properties of mesh to the extent the testimony centers on mesh's effect on and reaction to the human body. Ethicon's motion is **DENIED** on this matter.

In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., 2016 WL 4944991, at *3 (S.D. W. Va. Sept. 1, 2016).

Similarly, in the Court of Common Pleas in Philadelphia, Judge Arnold New denied Ethicon's motion to exclude Dr. Zipper's design defect opinions, including his opinions concerning mesh degradation and contraction. *See* Exhibit "C". Ethicon renewed its motion to exclude Dr. Zipper at trial. After hearing testimony concerning Dr. Zipper's qualifications and experience, Judge Mark Bernstein again denied Ethicon's motion, finding "[t]he witness is qualified to provide expert opinion testimony in his fields of expertise." *See* Exhibit "D" at 27:7-9.[2]

Likewise, this Court has repeatedly and consistently rejected similar *Daubert* challenges made by other mesh manufacturing defendants attacking other similarly qualified

[2] Notably, Judge Bernstein authored the comprehensive commentary on Pennsylvania Evidence.

urogynecologists who offer opinions based on the same or similar methodology as that employed by Dr. Zipper here. In *Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048 (S.D.W.Va. 2015), the Defendants sought to exclude Dr. Bruce Rosenzweig's opinions on the biomaterial properties of polypropylene based on the fact that he has no background in biochemistry and was therefore unqualified "to render opinions that 'deal with polymer science, biochemistry or biomaterials.'" *Id.* at 5. This Court denied that argument stating:

> [A]lthough Dr. Rosenzweig [expert urogynecologist who offered general causation opinions on the properties of polypropylene mesh, body's reaction to mesh, and complications] may not know the precisions of oxidative degradation, Dr. Rosenzweig has demonstrated extensive knowledge of and experience with the process of polypropylene mesh degradation in the body. He has performed "over a thousand pelvic floor surgical procedures," as well as "close to 300 surgeries dealing with complications related to synthetic mesh." And as he explained during his deposition, "I have explanted mesh. I have seen degraded mesh. I've seen hardened, brittled, fragmented mesh upon removal of mesh." Furthermore, Dr. Rosenzweig has read "close to the 2,000 papers that have been generated on midurethral slings." Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others.… Any gaps in Dr. Rosenzweig's knowledge go to his credibility, not his admissibility as an expert.

Id. at 5. As discussed below, Dr. Zipper has as much, if not more "knowledge of and experience with the process of polypropylene mesh degradation" than that of Dr. Rosenzweig.

Over the last 10 years, Dr. Zipper has trained over one-thousand urologists and gynecologists in the techniques of prolapse and incontinence surgeries. *See* Exhibit "E" at p. 4. Dr. Zipper has performed thousands of mesh and non-mesh incontinence and prolapse procedures. See *id.* at pp. 4-5 and Exhibit "D" at 14:23-15:1. Dr. Zipper has revised and/or explanted hundreds of mesh devices, including TVT-S (*id.* at 7) and has worked closely with SUI and POP mesh manufacturers to develop safer and more efficacious mesh products, including mini, single-incision slings like the TVT-S. *Id.* at 5 and 17-18.

While Dr. Zipper's surgical experience is beyond impressive, he has "spent much of his career commercializing and developing products," and has "expertise in material science" even though he is not a "material scientist." Exhibit "F" at 123:4-10. As stated by the doctor himself, "I have a[n] increased fund of knowledge that someone would consider a level of expertise in materials that I have used and/or tried to commercialize within my field of endeavor." *Id*. at 123:13-16. Furthermore, he has worked with engineers to develop and commercialize "[d]evices for the treatment of urinary incontinence, devices for the treatment of pelvic organ prolapse, devices for the treatment of overactive bladder disease, devices for the treatment of pelvic pain, [and] devices for the treatment of female sexual dysfunction and/or function." Exhibit "E" at 6. When developing these products, Dr. Zipper visits the manufacturer of the materials to be used in the device, and examines the manufacturing process and the materials produced. Exhibit "F" 124:6-125:9. On certain occasions, he reviews the *Material Data Safety Sheet* (MSDS) to see what kind of biocompatibility testing has been performed and looks at the physical properties of the material, e.g., the burst strength and elasticity. *Id.*

In addition to the above, Dr. Zipper necessarily keeps current on literature relevant to his practice, including the "breadth of medical literature that quite consistently demonstrates the material mismatch associated with polypropylene mesh; the concerns of heavier polypropylene meshes compared to the lightweight polypropylene meshes'; the concerns over pore size; concerns over the methods that it transgress and transit the obturator foramen in proximity to the obturator canal . . . ." Exhibit "G" at 40:7-14. Over the course of time, Dr. Zipper has read, "thousands and thousands of articles … that have led to the development of [his] opinion…." Exhibit "H" at 13:18-14:14. It is clear that Dr. Zipper's design defect opinions concerning TVT-S are based, in part, on this same method of exhaustively and thoroughly reviewing the medical

and scientific literature which he demonstrated in great detail throughout his Wave 6 general TVT-S expert report. *See e.g.* Exhibit "E" at pp. 79-261.

As a private independent consultant, Dr. Zipper has worked closely with engineers to develop devices and mesh products for the treatment of stress urinary incontinence and pelvic organ prolapse, many of which were subsequently developed and sold by foreign and U.S. medical device companies. Id. at 6. In this same role, he worked extensively to craft instructional materials and marketing materials for prolapse mesh and incontinence products. *See Id.* Dr. Zipper is currently the CEO of two medical device companies that develop medical devices used in female pelvic medicine and general surgeries. *Id*. at 5. In this role, Dr. Zipper drafts device labels using FDA and non-regulatory guidance documents – specifically, "ISO guidance, including 14 630." Exhibit I at 94:25-97:11.

Dr. Zipper has authored fifteen relevant patent applications and has been issued multiple patents relevant to the field of pelvic reconstructive surgery that are published by the United States Patent and Trade Office. *Id*. at 5.

Daubert' s focus is whether an expert has the "knowledge, skill, experience, training, or education" to opine on a subject. Dr. Zipper does not need to have a degree in "materials science" or practice exclusively in that field to be qualified to testify on the design of mesh and the characteristics of polypropylene. *See, e.g, Pineda v. Ford Motor Co*., 520 F.3d 237, 244 (3d Cir. 2008) (*citing Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777 (3d Cir. 2003). Dr. Zipper's collective knowledge, skill, experience, and training qualify him to do so.

II. Dr. Zipper's opinions on TVT-S's design defects, including polypropylene mesh characteristics is based on his knowledge, education, training and experience, including his extensive experience implanting mesh, treating its complications, and examining explanting mesh, as well as his thorough review of the medical literature, internal company documents and deposition testimony

In reaching his expert conclusions concerning polypropylene mesh characteristics, Dr. Zipper relies on his knowledge, education, training and experience implanting and explanting mesh devices, as well as his extensive review of the medical literature, internal company documents and deposition testimony.

Expert testimony based on personal observation should be considered reliable as long as the expert possesses specialized knowledge on which to base his opinion. *See Daubert*, 509 U.S. at 592-593. During an explant, Dr. Zipper first removes the explanted mesh from the pelvis. Exhibit "F" at 133:5-137:1. He then cleans the material of ingrained fibrous tissue, manipulates it, dissects the mesh for further examination, and compares it side by side to mesh which has not been implanted. *Id*. Based on his extensive education, training, and experience in pelvic prolapse as well as his study of scientific literature, Dr. Zipper is able to determine what changes have occurred in the mesh after implantation. *Id*. Dr. Zipper has previously testified, "the mesh I remove, the physical characteristics suggest or are very indicative of changes in the material properties of the mesh since the time of initial implantation to a more brittle, fragile, less elastic state." Exhibit "G" at 307:22-308:3. Furthermore, in preparing his reports, Dr. Zipper consults "a tremendous number of documents, an exhausting number of documents aside from my own clinic experience, my years of treating patients, implanting, explanting. . . ." Exhibit "F" at 114:9-14. His observations show that when "mesh comes out it is so altered, it is so shrunken, it is so brittle, it is so contracted that it's almost unrecognizable." *Id*. at 135:11-13. Additionally, he has "studied the contraction and shrinkage of mesh…through a review of the scientific literature, medical literature. And…my own investigation by evaluating the changes taking place in the products that I implant versus the products that I explant." *Id*. at 149:23-150:2. *See also* Exhibit "E" at pp. 214-225. He has also studied the flexibility of mesh before and after

implantation. As noted, in his product development role, Dr. Zipper would look at elasticity, tensile strength, and burst of mesh products. Exhibit F at 152:9-12.

Dr. Zipper's examinations are informed by his expertise. Dr. Zipper was qualified as an expert on urogynecology and pelvic products long before he ever became involved in litigation. His examinations and dissections of the mesh are reliable because they were done under typical scientific methods by a trained expert. This underlying expertise has been supplemented by his study of the documents "with great meticulousness." *Id.* at 116:14.

Despite the employment of this reliable methodology, Defendants make the same argument they lost in the past – that Dr. Zipper's "opinions concerning degradation, contraction, rigidity, and porosity" are unreliable because he still offers polypropylene mid-urethral slings to some of his patients. Def. Brf. at 7-8. Defendants make the similar argument with respect to Dr. Zipper's use of a polypropylene mesh called Alyte Y in abdominal sacrocolpopexies. While this might be fodder for cross examination at trial, this is not a basis for exclusion under *Daubert*, especially where – as here – Dr. Zipper painstakingly differentiates between the shorter, stiffer TVT-S polypropylene sling from full-length polypropylene retropubic mid-urethral slings that he still occasionally offers to a very select group of his patients. *See e.g.*, Exhibit I at 24:21-25:8; 25:17-21; 32:7-33:14.

Moreover, Dr. Zipper detailed additional critical design differences of the TVT-S from full-length mid-urethral slings including – importantly – the "defective nature of the fixation ends, the short length, the stiff laser cut mesh, and the sharp arrowhead inserter. These defects lead to both high failure and complications rates." *Id.* at 93:23-94:24 and Exhibit E at pp. 77, 87-150. Defendants' suggestion that Dr. Zipper's opinion in this regard is unreliable because – as

they suggest – he continues to use the same polypropylene mid-urethral slings in his patients today is, at best, erroneous and, at worst, a misrepresentation.

Regardless, this is the identical argument Defendants made in its prior challenge to Dr. Zipper (Exhibit "A" at 7) and which was appropriately denied by this Court, which stated: "Ethicon has not presented any compelling explanation as to why Dr. Zipper's biomaterials opinions are unreliable." *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4944991, at *3 (S.D. W. Va. Sept. 1, 2016). The Defendants' current argument fares no better, and should likewise be denied.

III. Dr. Zipper's opinion that there are safer alternative products is supported by sufficient facts.

Defendants' argument that Dr. Zipper has no basis to support his conclusions regarding safety and efficacy of an alternative design is baseless and should be rejected. With the exception of replacing "Prolift" and "Prosima" with "TVT-S", the Defendants current argument concerning Dr. Zipper's opinions regarding safer alternatives is identical to the argument made by Defendants in Wave 1 – even though Dr. Zipper's Wave 6 TVT-S expert report is considerably different than his Wave 1 Prolift/Prosima expert report. In Wave 1, the Court held that it was "without sufficient information to draw the fine line between reliable and unreliable expert testimony on this issue" and ultimately "reserved ruling until further testimony may be offered and evaluated firsthand at trial." *In re Ethicon Inc.*, 2016 WL 4944991, at *3 (S.D. W. Va. Sept. 1, 2016). Thus, while Plaintiffs respectfully request that this challenge be denied, at most, the Court should reserve ruling on this issue until further testimony can be elicited and evaluated first hand at trial.

Contrary to Defendants' argument on this issue, Dr. Zipper cites to numerous publications and internal documents demonstrating safer alternatives, including full-length mid-

urethral slings, non-mesh procedures, suture procedure and alternative designs using larger pore, lighter weight mesh (e.g., Ultrapro). For example, Dr. Zipper has opined that full-length mid-urethral slings, with or without Ultrapro, are safer alternative products than the short, stiff TVT-S product. Dr. Zipper's opinion in this regard is based, in part, on his experience with implanting thousands of various synthetic mesh products, his experience developing synthetic mesh products, his own studies on similar mini, single-incision slings and his experience explanting hundreds of mesh devices. *See* e.g. Exhibit "E" at 4-5,7, 8, 17-18.

But Dr. Zipper's opinion regarding safer alternative products was not limited to his experience alone. Indeed, Dr. Zipper dedicated nearly his entire 267-page Wave 6 TVT-S report to an exhaustive review of the medical literature, including his analysis of numerous randomized controlled trials ("RCTs") and systematic reviews of RCTs (level one evidence) which uniformly support his opinion that full-length midurethral synthetic mesh devices are a safer and more efficacious alternative than TVT-S. By way of example, Dr. Zipper relied on a study conducted by Dr. Krofta, et al that concluded "TVT-S appears to be less effective than TVT or TOT for surgical treatment of stress urinary incontinence in women. There was a surprisingly high incidence of urge incontinence and mesh erosion." *Id.* at 96. Dr. Zipper also relied on a systematic review of the literature (from 1996 to January 2011) for all randomized controlled trials (RCTs) comparing single incision slings (including TVT-S) to standard full-length midurethral slings which found that the "single incision sling to be associated with a significantly lower subjective and objective cure rate as well as higher reoperation rates for SUI" compared to full-length midurethhral slings and that SIS slings, including the TVT-S, had a "relative risk of repeat SUI surgery following SIS" that was "almost seven fold that of standard midurethral

slings" and that the "relative risk of mesh erosion following SIS was almost four fold that of standard midurethral slings." *Id*. at 106.

Other studies relied upon by Dr. Zipper which showed decreased efficacy and higher complications in the TVT-S compared to safer alternative full-length midurethral slings, including studies by:

- Neuman et al. who found de novo dyspareunia occurred in 7.9% of patients treated with the mini TVT-S sling compared to 0% in the women treated with Ethicon's full-length TVT-O device). *Id*. at 110-111.

- Dr. Piet Hinoul, Ethicon's own Worldwide Director of Medical Affairs, who found inferior efficacy and safety of the TVT-S compared to Ethicon's full-length TVT-O device. *Id*. at 118-123.

- Hota et al. (*Id*. at 123) – an RCT that was terminated premature due to serious safety and efficacy concerns – which found, *inter alia*:

    1) At one year, mesh extrusion was noted in 19% of the TVT-S group compared to 0% in the full-length TVT-O group.

    2) Resurgery for persistent or recurrent SUI occurred in 19% of the TVT-S group compared to 0% in the TVT-O group.

    3) Failure rates of TVT-S was 55% compared to 9% in the women treated with full-length TVT-O.

- Schimpf et al (a systematic review) which also found the TVT-S to be inferior and carried a higher risk of dyspareunia than full-length midurethral slings.

- Nambier et al (another systematic review of RCTs – level one evidence – by the Cochrane Group) which also found that the TVT-S was inferior and more dangerous than full-length midurethra slings. Id. at 133-137.

These are just a few examples from Dr. Zipper's expert report that demonstrate the intense analysis Dr. Zipper performed in rendering his opinions on safer alternatives. For an in-depth review of Dr. Zipper's opinions related to safer alternative midurethral slings, see Exhibit "E" at 79-261. Dr. Zipper performed a similar analysis concerning

other safer alternative products as he did above, including use of Prolene suture repairs (See e.g. *Id*. at 9-12, 16-17, 250) and use of lightweight, large pore slings, such as Ultrapro. *Id*. at 218-225, 241.

In this regard, Dr. Zipper testified as follows:

> Q: Doctor, do you have any opinion one way or the other whether or not a sutured device for treatment of stress urinary incontinence is a safer, more – a safe alternative design?
>
> A: Yeah, absolutely. I believe that there was a systematic review of the literature in 2009 and/or 2011 by the Cochrane Group that compared the efficacy of sutured-device type repairs such as the Burch procedure, conventional slings and midurethral slings and those systematic reviews found that all three procedures, the suture-device-type repair, the Burch repair, the traditional sling, and the synthetic midurethral sling all had similar efficacy, so they were equally effective. There was some – what they call variable and low level evidence to suggest that the synthetic repair had less short-term urinary tract symptoms, but there was no evidence of any long-term benefit from any one of those procedures over the other. So in the long term, the suture-device repair were equally effective and more likely than not safer.

Exhibit I at 97:12-98:8.

> Q: Doctor, do you have an opinion whether or not a full-length midurethral sling mechanically cut using Ultrapro would have been a safer alternative design than the TVT-Secur device?
>
> A: It would have been safer.

Thus, not only does Dr. Zipper's personal experience give him firsthand knowledge of those products that provide a safer alternative to the TVT-S, but his personal experience has been overwhelmingly confirmed by the medical literature and internal company document upon which he relies. A review of Dr. Zipper's expert report demonstrates the reliability of Dr. Zipper's opinions. Accordingly, Ethicon's motion should be denied or, in the alternative, a decision on this opinion should be reserved for trial as it was previously.

IV. Dr. Zipper is qualified to offer opinions concerning Ethicon's failure to provide adequate instructions for the safe use of the TVT-S, Ethicon's failure to

adequately warn physicians and patients of the serious risks associated with the TVT-S, and Ethicon's failure to adequately test the products before placing them on the market.

This Court has previously allowed Dr. Zipper to testify as an expert urogynecologist about the specific risks of implanting mesh and whether those risks appear on the IFU. *In re Ethicon Inc.*, 2016 WL 4944991, at *3 (S.D. W. Va. Sept. 1, 2016). However, the Court limited his testimony to the above issues but would not allow him to testify regarding industry standards as they relate to the IFU stating that "[w]hile an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Id*. (citing *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015)).

Plaintiffs respectfully request this Court reconsider its prior ruling based on Dr. Zipper's recently acquired additional expertise, as an executive in the medical device industry who has meaningful experience in drafting IFU's for medical devices, from an industry perspective, on what information manufacturers should or should not include in an IFU regarding safety issues, risks, warnings, efficacy analysis and validation from an industry and not regulatory perspective. Dr. Zipper, is not only a clinical urogynecologist, but is a manufacturer/owner executive and developer of medical devices and works on drafting IFU's for these products as set out below.

Dr. Zipper is presently drafting IFU's for the new accessories for a 510(k) cleared laser to be sold by Uroshape, LLC. The type of information that Dr. Zipper must take into consideration in drafting the IFU, is from an industry standard perspective, not from the FDA's perspective. Dr. Zipper is also the current CEO of BioFuse Medical Technologies, LLC . BioFuse Medical Technologies, LLC develops proprietary bipolar RF technology for use in FMPRS [female pelvic

and medical reconstructive surgery] and general surgery. It owns and will sell a 510(k) cleared proprietary RF generator for vessel sealing. Dr. Zipper is currently drafting IFUs for this device. See Exhibit "E" at p.5; Exhibit "I" at 14:2-24; 94:25-97:10.

Dr. Zipper testified that his methodology for drafting labels relies on the code of federal regulations, part 801 established by the FDA, the adjoining guidance G91-1 which includes the ISO guidance, and he then applies all those to the medical device label as the minimum requirements. Dr. Zipper strives to assure that the label contains terms that patients can understand; makes sure to inform users about what is known and what is not known; what clinical trials are missing and what clinical trials are available. He will test the label first among his coworkers and then once they're done, its tested among the end users. Dr. Zipper may ask key opinion leaders to be part of design validation but design validation of these medical device labels will include enough true users of the device. Dr. Zipper opined that the only way that you can adequately test a label is to include true users of the device. *Id*. at 96:13-97:6. Dr. Zipper uses that methodology in his practice as a CEO executive board member of device manufacturing companies. *Id***.** at 97:7-11.

Therefore, Dr. Zipper now has additional hands on, meaningful experience in drafting IFU labels for medical devices using the required industry standards – specifically, the ISO guiding documents. Dr. Zipper now has experience as an executive for two medical device companies who is involved in drafting medical device labels; is familiar with the type of information that should be communicated to surgeons and users of medical devices, and from an industry perspective so that surgeons can make reasonable informed choices when considering the implantation of medical products such as TVM devices. In addition, Dr. Zipper has read and is familiar with the IFU's, sales and marketing materials, and physician training materials,

including videos prepared by Bard for its mesh products; and has also reviewed the IFUs for other transvaginal mesh products that he has implanted in his practice of FPMRS. Exhibit "E" at p. 7.

As such, Dr. Zipper has the expertise to offer opinions concerning the adequacy of Ethicon's IFUs and applied the same reliable methods he uses as the CEO of two medical device companies. Therefore, Dr. Zipper should be permitted to offer opinions concerning the adequacy of Ethicon's TVT-S IFUs and other labeling materials in this case.

Even if not considered an expert *per se* in product warnings—which he is—his opinions on the inadequacies of the IFU are still admissible based on his extensive experience as a urogynecologist that is board certified in pelvic reconstruction surgery and who has treated hundreds of patients having mesh related complications. This Court has previously ruled that an individual proffered as an expert in product warnings need not be an expert *per se* so long as they have extensive experience treating patients with mesh related complications. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-704, 719-720 (S.D.W.Va. 2014). Accordingly, Ethicon's motion should be denied.

V. Plaintiffs will abide by the Court's prior rulings on opinion testimony relating to Ethicon's knowledge, state of mind or alleged bad acts and will not elicit any such testimony from Dr. Zipper.

VI. Dr. Zipper's opinions will be based on his review of internal company documents and medical literature that he has demonstrated provide support for his opinion that the TVT-S is defectively designed, that Ethicon failed to adequately test the TVT-S before launching the device and, to the extent permitted, that Ethicon failed to provide adequate warnings of the risks of the TVT-S.

Plaintiffs acknowledge that the Court has cautioned the parties against introducing corporate evidence through expert witnesses. *In re Ethicon Inc.*, 2016 WL 4944991, at *5 (S.D. W. Va. Sept. 1, 2016). However, to the extent Dr. Zipper discusses corporate evidence at trial,

he will do so solely for the purpose of explaining the basis for otherwise permissible expert opinions – which this Court has found to be permissible. *Id*. Dr. Zipper will not offer testimony that is solely a conduit of corporate information.

Conclusion

Dr. Zipper is qualified due to his long practice in urogynecology as well as his unique experience in acting as a product design consultant for his own company and numerous other pelvic mesh manufacturers; therefore, he is qualified to testify in these cases. In addition to his knowledge, education, training and experience, Dr. Zipper thoroughly analyzed the medical literature, internal company documents and deposition testimony. As his report and deposition testimony demonstrate, Dr. Zipper applied a reliable methodology in order to reach the sound opinions expressed in his expert report and during his deposition. As such, Defendants' motion to exclude certain opinions of Dr. Zipper should be denied.

Dated: December 8, 2017

/s/ Bryan F. Aylstock
Bryan F. Aylstock
Florida Bar No. 78263
Aylstock, Witkin, Kreis & Overholtz, PLLC
17 E. Main Street, Suite 200
Pensacola, Florida 32502
(850) 202-1010 Telephone
(850) 916-7449 Facsimile
baylstock@awkolaw.com
ATTORNEY FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 8th day of December, 2017, this document was filed with the Clerk of Court using the Florida Courts E-Filing Portal system, which will serve a true and correct copy of the same, together with a notice of electronic filing, on all counsel of record. A copy has also been served on all counsel of record on the attached service list.

/s/ Bryan F. Aylstock
Bryan F. Aylstock
Florida Bar No. 78263
Aylstock, Witkin, Kreis & Overholtz, PLLC
17 E. Main Street, Suite 200
Pensacola, Florida 32502
(850) 202-1010 Telephone
(850) 916-7449 Facsimile
baylstock@awkolaw.com
ATTORNEYS FOR PLAINTIFFS